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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,014	09/15/2003	Achim H. Krauss	17619 (AP)	1736

7590
Robert J. Baran (T2-7H)
ALLERGAN, INC.
Legal Department
2525 Dupont Drive
Irvine, CA 92612

07/13/2007

EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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07/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/663,014	Applicant(s) KRAUSS, ACHIM H.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of amendment, response and declaration all dated 4-24-07 is acknowledged.

Claims 1-11 are pending. Claim 11 has been newly added.

Terminal Disclaimer

The terminal disclaimer filed on US 7,070,768 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of July 04, 2006 has been reviewed and is accepted. The terminal disclaimer has been recorded.

In response to the amendment the following rejection of record has been applied to only claim 11 (new claim):

Claim Rejections - 35 USC § 112

Claims 11 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for converting gray hair to the original pigment in the hair follicle of a subject being treated by the instant composition, does not reasonably provide enablement for preventing graying of hair. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Instant claim broadly recites a method of preventing graying of hair, which denotes that administering the instant composition is stopping the process of gray once. Gray hair is caused due to a number of reasons, such as predisposing genetic factors, exposure to UV radiation, natural aging process etc. Further, despite the fact the

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external or physical causes such UV radiation from sunlight do not always result in gray hair in each and every individual exposed to the radiation. Further, there is no specific time line or age at which graying can occur in different individuals. The instant term "prevention" denotes that the graying process does not occur again during the lifetime of a subject undergoing the instant treatment. A review of the instant specification does not reveal that the experimental data provided includes testing the composition for a period of six months or less, which shows that the gray hair is converted to a dark brown pigment in treated subjects. Thus, the present "prevention" has been shown to be effective for 6 months as opposed to the physiological process of graying of hair which happens over a period years, depending on partial graying or complete graying of hair. Further, applicants have not shown that after 6 months, if the treatment is effective for any length of time i.e., years and that the treatment is successful in completely stopping from gray hairs to appear again. Absent such a data and also in the absence of any description as to the dosage, duration of treatment, age of the subjects etc., one of an ordinary skill in the art would have to perform undue experimentation to practice the claimed prevention of gray hair because one does not know the required duration of the claimed treatment so as to achieve the "prevention". The instant disclosure enables a skilled artisan in only treating gray hairs with the claimed composition so as to convert the pigment in the hair follicles to original color for about six months period but does not enable a skilled artisan to continue the treatment for ever so as to permanently convert the pigment to original color. For prosecution purposes, instant term "preventing" is construed as "treating".

RESPONSE: Applicants argue that the examiner equates the claimed graying, is a result of UV radiation and explains that graying is a result of any of the conditions cited by examiner. As also mentioned in the above rejection, examiner acknowledged that the process graying is a result of a number of factors and not just by UV radiation. For the same reason, the rejection also explained that not all the causes of graying result in gray hair at the same time and at the same rate in different individuals or subjects. Given the variation in the time line of graying and given the lack of teaching or guidance as to when, how and for duration does the treatment be given, one cannot predict the efficacy of the treatment claimed. Applicants argue that instant method is not limited to a single treatment and do not exclude as many times as necessary. However, neither instant claims nor specification describe as to duration of the application for a complete "prevention". Instant example 1 describes that "a significant portion" of the hairs turned to original color, suggesting that not all the hairs turned to original color. Further, in example 3, the volunteer tested shows part gray and part dark brown hairs, suggesting that a complete reversal of gray hair has not occurred at the end of testing period. Thus, instant claims are not enabled for prevention of gray hair and instead only treatment.

The following new rejection is applied to claims 1-11:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over the article New drugs of 2001 (J Amer. Pharm. Association 2002) by itself or in view of Ortonne et al (Pigmentation of Hair 1993).

The above article entitled "new Drugs of 2001" discloses two new drugs for glaucoma, bimatoprost and travoprost of which the former is within the scope of the instant claims (see claim 4). The article teaches that the compound bimatoprost is useful in reducing the intraocular pressure (page 2). However, the side effects of the compound included among others, darkening of eyelashes, eyelash growth and pigmentation (page 3). Thus, the compound of the instant invention is known for increasing the pigmentation and darkening of hairs (eye lashes). The article also teaches 0.3% bimatoprost (claim 2) as a solution (claim 9). While the above article fails to teach the claimed method per se, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ bimatoprost for increasing

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pigmentation or darkening of eyelashes or hair because the compound bimatoprost and in general prostaglandins (page 1) are known to increase pigmentation of skin and hair by increasing the number of melanosomes.

Alternatively, Ortonne studied the ultra structural and biochemical aspects of hair color and teaches that hair pigmentation is caused by melanin pigment produced by melanosomes (introduction). Table 1 of Ortonne shows that level of tyrosinase activity and the levels of eumelanin and pheomelanin dictate a wide variety of hair colors. Ortonne further teaches that grey hair refers to depigmentation (page 878-879). Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ bimatoprost for increasing pigmentation or darkening of eyelashes or hair because Ortonne suggests loss of melanin pigmentation (depigmentation) results in grey hair and that the synthesis of different melanin pigments in melanosomes contribute the variety of hair colors. A skilled artisan would have expected to increase melanin pigment production in melanosomes, with bimatoprost, and thus would have expected an increased pigmentation with the administration of bimatoprost.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

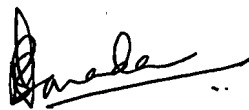
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615
July 10, 2007



LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER